

REMARKS

Claims 1-37 are pending. Claims 6-26 are withdrawn. Claims 1-5 and 27-37 are rejected. Claims 5 and 31 are canceled without prejudice.

Applicants submit herewith a supplemental Information Disclosure Statement to document the requested publication date (February 12, 2008) of the previously submitted International Search Report.

CLAIM OBJECTIONS

Claims 1, 6-27, 30, and 32-35 are objected to for informalities. Applicants have amended the claims as required to respond to the objections.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

Claims 1-5 are rejected under 35 U.S.C. §112 ¶1 as not enabling.

Claim 5 is canceled, rendering its rejection moot.

With respect to claims 1-4, they now recite that the composition minimizes adhesion. Support for the amendment is found at least at ¶14, thus introducing no new matter. Applicants respectfully assert that a person of ordinary skill in the art would recognize that the claimed composition minimizes adhesion of the wound covering to the wound, relative to a wound covering lacking the claimed composition.

However, to further support this assertion, Applicants submit with this Amendment two Declarations under 37 C.F.R. §1.132. They state, *inter alia*, that hyaluronate is hydrophilic and thus retains moisture which keeps the wound surface moist. A moist wound surface minimizes adhesion to, for example, a bandage. The composition maintains hyaluronate, particularly high molecular weight hyaluronate, at the wound surface longer. Specifically, the Enclosures provide data demonstrating the claimed composition's ability to maintain high molecular weight hyaluronate at the wound surface. By maintaining hyaluronate at the wound surface longer, the composition maintains a moist wound surface, and thus minimizes adhesion.

For at least these reasons, Applicants respectfully assert that claims 1-4 are enabled and respectfully requests withdrawal of the rejection.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 1-5 and 27-37 are rejected under 35 U.S.C. §103(a) as obvious over Hollingsbee in view of Tsubouchi.

Claims 5 and 31 are canceled without prejudice, thus rendering their rejection moot; their limitations are incorporated into claims 1 and 27, thus introducing no new matter.

With respect to the rejection of claims 1-4, 27-30, and 32-37, Applicants respectfully disagree. Hollingsbee teaches a dry film for topical use in treating wounds. In contrast, Applicants' amended claims recite a composition in the form of a sterile aqueous solution or a gel. Hollingsbee teaches away from Applicants' composition in distinguishing its (Hollingsbee's) composition from other compositions:

These [other referenced] compositions are however in the form of emulsions or hydrogels. When used in the treatment of wounds these product forms can suffer from the disadvantage that they add liquid to the wound site which adds to the problem of management of wound exudate. In addition these product forms make it difficult to apply a known and uniform dose to the wound (Hollingsbee p. 1, lines 27-33)

Hollingsbee teaches advantages of his dry films, in contrast to such "emulsions or hydrogels":

The advantages of this [Hollingsbee's] film are that because the film is dry, exudate is readily absorbed by both the hyaluronic acid and the hydrocolloid and dosing is uniform and predictable (p. 2, lines 21-24).

Thus, Applicants respectfully assert that Hollingsbee does not teach, suggest, or motivate, and a person of ordinary skill in the art would not predict, Applicants' composition because Hollingsbee specifically teaches away from Applicants' solution or gel.

The secondary Tsubouchi reference does not cure Hollingsbee's deficiencies. Tsubouchi, like Hollingsbee, teaches use of a dry film as a wound dressing. Therefore, Applicants respectfully assert that Hollingsbee in view of Tsubouchi does not render Applicants' composition obvious, at least because neither Hollingsbee nor Tsubouchi teach a sterile aqueous solution or a gel, and teach away from the use of a sterile aqueous solution or a gel as a wound healing composition.

Applicants' composition cannot be formulated as a dry film, as Hollingsbee and Tsubouchi teach, as demonstrated in Applicants' Declaration 1. Drying Applicants' film drives off iodine and, therefore, prevents formation of Applicants claimed composition of hyaluronic acid, iodine, and potassium iodide. Specifically, Enclosure I, cited in Declaration 1, demonstrates that in a dry film, within 24 hours, about 80% of the iodine is evaporated. Thus, a dry film, as Hollingsbee teaches, cannot maintain Applicants' composition of iodine, potassium iodide, and hyaluronic acid.

Applicants' composition is based on the unexpected finding that the combination of iodine, potassium iodide, and hyaluronic acid provides a superior wound healing composition with minimized wound adhesion. In further support, Declaration 1 analyzes how the combination of iodine and iodide results in the formation of potassium triiodide which stabilizes the hyaluronate. Applicants provide data that further demonstrate the composition provides synergistic healing effects when compared to the individual components (Enclosures II-IV), and that a person of ordinary skill in the art would not look to iodine/potassium iodide as a disinfectant based on their historical shortcomings (Enclosures VI-IX).

For at least these reasons, Applicants assert that Hollingsbee, in view of Tsubouchi, does not render Applicants composition obvious, and that the rejections of claims 1 and 27, and dependent claims 2-4, 28-30, and 32-37, are overcome. Applicants thus respectfully request their withdrawal.

CONCLUSION

The application is believed to be in complete condition for allowance. Applicants authorize credit card payment of the fee for a one-month extension and supplemental IDS (see Electronic Fee Calculation sheet). No other fees are believed due but, if deemed necessary, the Office is authorized to charge them to Deposit Account No. 20-0809.

The Examiner is invited to telephone Applicants' undersigned representative with questions.

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